REMARKS

The Examiner stated that if applicants desire to claim priority under 35 USC 120, specific reference to the earlier application must be made in the instant application. This application is actually a 371 national stage application. Accordingly, the specification has been amended to include this information.

The Examiner has stated that the references in the specification were not considered because they were not submitted in a proper information disclosure statement. Applicants are submitting an Information Disclosure Statement that includes the references cited in the specification. Accordingly, these references should be considered by the Examiner.

Claim 38 stands rejected under 35 USC 112, second paragraph, because the Examiner finds the term "agent" vague and indefinite. Specifically, the Examiner states that "[i]t is not clear what other ingredients are present in addition to the claimed recombinant constructs and what form the agent takes." This rejection is respectfully traversed.

An agent is a well known term in the art for an active substance that induces, enhances or otherwise stimulates a response as recited in claim 38. The Examiner has not presented a factual basis to support the rejection. Further, claim 38 also defines the agent as "comprising a recombinant viral construct according to any one of claims 1-8." Accordingly, any active substance that includes one of the claimed constructs is included in claim 38.

Claims 36 and 37 stand rejected under 35 USC 101 as being directed toward non-statutory subject matter. Claims 36 and 37 have been cancelled. Accordingly, this rejection is now moot.

Claims 1-8, 17-20 and 38 stand rejected under 35 USC 103(a) as being unpatentable over Paoletti in view of Ramshaw. This rejection is respectfully traversed. Claims 1-8, 17-20 and 38 all recite an avipox viral vector incorporating an HIV antigen and a cytokine. The Examiner states that Paoletti provides "avipox viral vectors encoding lentiviral (e.g. HIV, SIV) gene products (e.g., Gag Pol, Env) that are suitable for inducing viral-specific immune responses."

However, the Examiner admits that Paoletti fails to disclose using the avipox viral vector incorporating an HIV antigen with a cytokine.

According to the Examiner, Ramshaw provides recombinant viral vectors carrying a first nucleic acid encoding a viral immunogen and a second nucleic acid encoding a cytokine adjuvant that facilitates the immune response to the immunogen. It is the Examiner's contention that it would have been obvious to combine the avipox viral vector disclosed in Paoletti with the cytokine disclosed in Ramshaw. The Examminer contends that it would be reasonable to make the combination "since this would reasonably be expected to enhance the immune response to the HIV-1 antigen of interest."

As explained in the "Background of the Invention" simple avipox viral vaccines have been prepared, however, the response is "often weak, transient or non-existent." Accordingly, prior to applicants' invention there was no expectation in the art that these vaccines could be effectively used. Paoletti does not mention or suggest any methods that can be used to enhance their effect. Further, although Ramshaw describes using cytokines, Ramshaw does not suggest that they can be used for enhancing the effect of an avipox viral vector.

The Examiner's stated motivation is so general in the context of the relevant art as to constitute no more than the reference to a general level of skill in the art found deficient in In re Lee, previously cited and quoted by applicant. As emphasized by the court in *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002), the Examiner must present specific evidence of motivation, not the generalized evidence relied on in the pending Action:

> When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the *Graham* factors).

The burden imposed by Lee is not an impossible burden, as explained by the court in In re Thrift, 298 F.3d 1357, 1364-65, 63 USPQ2d 2002 (Fed. Cir. 2002), with respect to the references relied on by the Board in that case:

> In the present case, the reasoning articulated by the Board is exactly the type of reasoning required by In re Lee. Both the examiner and the Board clearly identified a motivation to combine the references, stating that the skilled artisan would have "found it obvious to incorporate the speech input and speech recognition techniques taught by Schmandt into the expert system of Stefanopoulos in order to reduce the need for less user friendly manual keyboard and mouse click inputs." Decision on Appeal at 5; accord Aug. 7, 1996 Office Action at 3. The motivation to combine the references is present in the text of each reference. The Schmandt reference itself verifies this motivation, stating that "allowing users to remain focused on the screen and keyboard, instead of fumbling for the mouse, would be beneficial in a workstation environment." Schmandt at 51. Stefanopoulos itself, while not expressly disclosing the use of speech recognition, sets forth the motivation to combine the references, stating that "there are alternative means to select the buttons, including . . . voice-activated transfer means, which may be readily adapted for use with the present invention by those skilled in the art." '237 patent, col. 4, ll. 34-38.

The reliance in the pending Action on the assertion that cytokines could be expected to enhance the immune response of the antigen of interest comes nowhere close to the analysis required by *Lee* and approved in *Thrift*. The Examiner has pointed to no disclosure in either Paoletti or Ramshaw that is evidence of that cytokines can be used to enhance the effect of an avipox viral vector. The failure of the Examiner to adequately support the combination of Paoletti and Ramshaw requires that this rejection be withdrawn.

Claims 9-16 and 21-37 stand rejected under 35 USC 112, first paragraph, as containing subject matter which was not enabled by the specification. According to the Examiner, the specification is non-enabling because: 1) the state-of the art relative to HIV vaccine development is replete with failure; 2) The disclosure fails to provide adequate guidance pertaining to protective immunity; 3) the disclosure fails to provide adequate guidance pertaining to suitable immunogens, adjuvants, routes of administration, and immunization regiments; and 4) the disclosure fails to provide any working embodiments.

The test for enablement is clearly spelled out in *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), which states that: "The test of

enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." See also MPEP 2164.01, which adds that "A patent need not teach, and preferably omits, what is well known in the art."

As described in the Background of the Invention, "simple recombinant avipox vaccines (without co-expression of cytokines)" are known. Accordingly, the Examiner's assertion that more disclosure is needed because of the uncertainty of HIV vaccines and because of lack of guidance for using the claimed construct is not applicable (and there on the face of the specification) because one reasonably skilled in the art already knows how to prepare and use avipox vaccines that have sometimes shown some weak and transient effects. Accordingly, since these vaccines are known, creating and using the claimed construct would not require undue experimentation to one reasonably skilled in the art.

Further, as to the failure to provide any working embodiments, MPEP 2164.02 makes it clear that:

> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Accordingly, since one skilled in the art would know how to make and use the claimed construct, this rejection should be withdrawn.

For the foregoing reasons, a notice of allowance is solicited.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 229752001400.

Respectfully submitted,

Dated: June 15, 2004 By: _____

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